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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/552,069	07/14/2006	Torsten Almen	Q90475	6111

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EXAMINER	
SCOTT, ANGELA C	
ART UNIT	PAPER NUMBER
1767	

NOTIFICATION DATE	DELIVERY MODE
06/10/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/552,069	ALMEN ET AL.	
	Examiner	Art Unit	
	Angela C. Scott	1767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 February 2011*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4,6-11 and 13-54* is/are pending in the application.

4a) Of the above claim(s) *18-41* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4,6-11,13-17,42,43,45 and 49-54* is/are rejected.

7)☒ Claim(s) *44 and 46-48* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 11, 2011 has been entered.

Applicant's response submitted on February 11, 2011 has been fully considered. Claim 54 has been amended. Claims 1, 4, 6-11 and 13-54 are pending with claims 18-41 withdrawn from consideration.

Claim Rejections - 35 USC § 102/103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 6, 16, 17, 43, 45-47, 49, 53 and 54 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Lidgren (US 6,586,009).

Regarding claims 1, 43 and 45, Lidgren teaches a bone cement containing a liquid component containing a polymerizable substance and a powder component containing a plastic substance and an X-ray contrast medium (Abstract), such as iohexol (a non-polymerizable organoiodine compound) (Col. 2, lines 65-67).

While Lidgren does not explicitly teach that the iohexol is incorporated into the particles of the particulate polymer, it is mixed with the particulate polymer. While a claim may be limited by and defined by a process, i.e., incorporation of iohexol into the particles of the particulate polymer, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). In this case, it is the position of the Office that the claimed product is the same as, or so similar as to be an obvious variant of, the product of the prior art.

Regarding claim 6, Lidgren teaches that an antibiotic compound is added to the composition (Example 4).

Regarding claims 16 and 17, Lidgren teaches that the polymer particles of the particulate polymer portion have a particle size of around 80-100 μm (Example 1). Since the particle size of the polymer varies between 80 and 100 microns, it is polydisperse.

Regarding claim 49, Lidgren teaches in Example 2 that the powder component contains between about 5 and about 40 percent by weight of the x-ray contrast medium (organoiodine compound).

Regarding claims 53 and 54, Lidgren teaches that the particulate portion is made of acrylic polymer particles, preferably polymethylmethacrylate and/or copolymers containing polymethylmethacrylate (Col. 3, lines 10-15).

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 4, 9-11, 42, 50 and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lidgren (US 6,586,009) as applied to claim 1 above.

Lidgren teaches the bone cement of claim 1 as described above. Lidgren additionally teaches that the liquid and powder components are adapted to be mixed and thereby provide a setting mass which is set to form the cement (Col. 2, lines 50-55). The Office takes Official Notice that one of ordinary skill in the art would mix these components until they are homogeneously distributed, meaning that the chemical substances are present in both components in concentrations that differ by less than 50%, most preferably by less than 10%, in order to provide the advantages of this composition.

Claims 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lidgren (US 6,586,009), as applied to claim 1 above, and further in view of Posey-Dowty et al. (US 5,258,420).

Lidgren teaches the bone cement of claim 1 as described above. Lidgren additionally teaches that an antibiotic compound is added to the composition (Example 4).

Lidgren does not teach that the antibiotic compound is specifically in the form of a lipophilic ester such as erythromycin. However, Posey-Dowty et al. teaches bone cement compositions containing preferably erythromycin as the antibiotic (Col. 3, lines 52-56). Lidgren and Posey-Dowty et al. are analogous art because they are from the same field of endeavor, namely that of bone cement compositions. At the time of the invention, a person of ordinary skill in the art would have found it obvious to use erythromycin as the antibiotic, as taught by Posey-Dowty et al., in the composition, as taught by Lidgren, and would have been motivated to do so because this antibiotic works well in these types of compositions to be released in a sustained high concentration (Col. 2, line 50).

Claims 13 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lidgren (US 6,586,009), as applied to claim 1 above, and further in view of Wenz (DE 20218668). For convenience, the citations below are taken from the English language equivalent US 2005/0287071.

Lidgren teaches the bone cement of claim 1 as described above. Lidgren does not teach that the liquid portion or that the particulate polymer portion comprises at least one of hydroquinone, growth hormone, bone morphogenic protein, or vitamins. However, Wenz teaches a bone cement composition that contains, in either the liquid or powder component, a bone morphogenic protein compound (¶29). Lidgren and Wenz are analogous because they are from the same field of endeavor, namely that of bone cement compositions. At the time of the invention, a person of ordinary skill in the art would have found it obvious to use a bone morphogenic protein, as taught by Wenz, in the composition, as taught by Lidgren, and would have been motivated to do so because it helps induce the formation of bone and cartilage.

Claims 14 and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lidgren (US 6,586,009), as applied to claim 1 above, and further in view of Nies et al. (US 5,650,108).

Regarding claim 14, Lidgren teaches the bone cement of claim 1 as described above. Lidgren does not teach that the liquid portion is present in a range of from 25-45% by weight. However, Nies et al. teaches a bone cement composition comprising from 2 to 50% by weight of a liquid component (Col. 3, lines 30-35). Lidgren and Nies et al. are analogous art because they

are from the same field of endeavor, namely bone cement compositions. At the time of the invention, a person of ordinary skill in the art would have found it obvious to use the above amount of liquid component, as taught by Nies et al., in the composition, as taught by Lidgren, and would have been motivated to do so in order to obtain the appropriate viscosity of the mixture (Col. 5, lines 55-60).

Regarding claim 52, Lidgren teaches the bone cement of claim 1 as described above. Lidgren does not teach that the monomer-containing liquid portion comprises acrylic acid, methyl acrylate, ethyl acrylate, methacrylic acid, methyl methacrylate, butyl methacrylate or styrene. However, Nies et al. teaches a bone replacement material wherein the liquid component comprises an acrylic and/or methacrylic acid ester monomer (Col. 3, lines 30-35). At the time of the invention, a person of ordinary skill in the art would have found it obvious to use acrylate monomers, as taught by Nies et al., to form the liquid portion of the bone cement, as taught by Lidgren, and would have been motivated to do so because these types of monomers work well in bone cements and to ensure good mixing with the particulate portion of the Lidgren composition, as it is also made from acrylate monomers.

Allowable Subject Matter

Claims 44 and 46-48 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter:

In claim 44, the R^6 group of the organoiodine compound of formula (IV) must EACH be a triiodophenyl group attached via a 1 to 10 atom bridge composed of bridging atoms selected from O, N, and C. This type of structure is not found in, nor is obvious from, the prior art of record. The prior art does teach compounds where one of the R^6 groups is a triiodophenyl attached via a bridge, but not where all of the R^6 groups are this moiety.

In claims 46 and 47, the organoiodine compound is an acylated derivative of a compound such as iohexol or iopamidol. The acylated derivatives of these compounds used by the applicant are made by them. The prior art of record does not teach these compounds, nor are they obvious from the prior art of record.

In claim 48, the organoiodine compound must be either iopamidol pentaacetate, iohexol hexaacetate or iodixanol nonoacetate. Applicant synthesizes these compounds for the bone cement. The prior art of record does not teach these compounds, nor are they obvious from the prior art of record.

Response to Arguments

Applicant's arguments filed February 11, 2011 have been fully considered but they are not persuasive.

Applicant's argue that they have achieved unexpectedly superior results with their invention and have submitted a Rule 1.132 Declaration as evidence to that end. The declaration was submitted to show that when a preferred organoiodine compound was incorporated into the polymer particles of the invention that an unexpected superior result was achieved as opposed to only mixing compounds such as iohexol and iodixanol with the polymer particles. The declaration is unpersuasive.

In response to applicant's argument that the instant invention has achieved unexpected results, the Office points out that enhancing and improving upon existing properties is not necessarily equated to the generation of unexpected results. Any differences between the claimed invention and the prior art may be expected to result in some differences in properties. The issue is whether the properties differ to such an extent that the difference is really unexpected. *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). See MPEP §716.02. Additionally, whether the unexpected results are the result of unexpectedly improved results or a property not taught by the prior art, the "objective evidence of nonobviousness must be commensurate in scope with the claims which the evidence is offered to support." In other words, the showing of unexpected results must be reviewed to see if the results occur over the entire claimed range. *In re Clemens*, 622 F.2d 1029, 1036, 206 USPQ 289, 296 (CCPA 1980). MPEP 716.02(d). In this case, only one compound of the invention is shown, the iohexol hexaacetate compound. Claim 1 covers a much broader range of compounds, including iohexol and iodixanol. In order to be commensurate in scope with claim 1, more compounds must be tested or the claim must be amended to only include iohexol hexaacetate. Additionally, there appears to be some overlap in the min-max ranges for each comparison of bone cements

meaning that sometimes the compounds tested have a similar strain. More examples of the invention would help to distinguish this invention from that of the prior art as would more narrow and definite claim language defining the organoiodine compound.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Angela C. Scott whose telephone number is (571)270-3303. The examiner can normally be reached on Monday through Friday, 8:00 am to 5:00 pm, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Eashoo can be reached on (571) 272-1197. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mark Eashoo/
Supervisory Patent Examiner, Art Unit 1767

/A. C. S./
Examiner, Art Unit 1767
June 2, 2011